

REMARKS

In response to the Examiner's rejections, claims 9 and 21 have been cancelled, and claims 1 – 5, 7, 10 – 13, and 15 – 20 have been amended to define the subject matter which applicant regards as the invention, and to distinguish over the prior art cited by the Examiner.

Antecedent basis for amending claims 1, 7, 16, and 17 to include method of fabrication is provided by the specification at paragraph 0017, line 1.

Antecedent basis for amending claims 2, 11, and 19 to include connecting means is provided by the specification at paragraph 009, lines 6 – 8.

Antecedent basis for amending claims 3, 12, and 20 is provided by **FIGURE 1**, which clearly shows connecting means **12** to be a flange.

No new matter has been added.

On Jan. 23, 2004, applicant submitted a corrected drawing of **FIGURE 1**, with reasons for the correction. Substitution of the corrected drawing for the original drawing is respectfully requested.

APPLICANT'S ARGUMENTS FOR PATENTABILITY

Claim 1 (currently amended)

Claim 1 recites a tubular member having an outside diameter of from about ten to about one hundred microns, and an inside diameter of from about five to about fifty microns; and specifies that the tubular member is fabricated by metallic electrodeposition (lines 2 – 5). The dimensions or size of the tubular member, and the method of fabrication are interrelated: metallic electrodeposition is the only method known to the applicant by which a tubular member of these dimensions can be fabricated. The patent to Kwan discloses neither microdimensions nor a similar method of fabricating the disclosed hollow drill. Indeed, to function as a dental drill, the hollow drill must necessarily be larger than applicant's claimed tubular member by several orders of magnitude. The hollow drill must necessarily have dimensions of the order of centimeters or millimeters, whereas the claimed tubular member has dimensions of the order of thousandths of a millimeter. This represents a difference of at least three orders of magnitude.

In response to the Examiner's statement that "A change in size is generally recognized as being within the level of and skill in the art," applicant agrees that, within an order of magnitude, the Examiner's statement is, in general, correct. Applicant submits, however, that when the difference in size is of several orders of magnitude, it can not be assumed that such a change in size lies within the level of and skill in the art. To the contrary, physical science is replete with examples where a change in size of several orders of magnitude results in entirely different and often unexpected properties: colloids, Brownian movement, wave properties of a material particle, and many more. Technology also provides many such examples; viz., the penetrating point of a needle or pin, the cutting edge of a knife blade, etc. In this particular instance the very small size of the microtube—dimensions of the order of microns—is a critical and necessary feature of the microtube for effective and novel use in such surgical and dental procedures as a root canal, where operational space is necessarily at a minimum. It is recognized that, when the size and dimensions are a critical or an essential part of the invention, size and

dimensions are a proper basis for novelty, non-obviousness, and patentability. Ortho Kinetics, Inc. v. Safety Travel Chairs, Inc., 1 USPQ 2d 1081 (Fed. Cir. 1986). The present invention is clearly such a case.

Reconsideration, withdrawal of the rejections, and allowance of claim 1 as amended are respectfully requested.

Claim 2 (currently amended)

Claim 2 recites “means for connecting the posterior end of the tubular member to a source of the therapeutic agent.”

The hollow drill disclosed by Kwan has no means of connection to a source of a therapeutic agent. To provide such an agent, e.g. an anesthetic, it is necessary to remove the adapter and hand piece, and to insert a conventional dental needle for the injection of anesthetic or other solution via the perforations in the hollow drill. (Abstract). Using a conventional dental syringe, the dental needle is inserted into the drill, and the required quantity of anesthetic solution slowly injected into the cancellous [cancerous] bone. (Operation FIG. 1, copy attached).

The provision of a means for connecting the microtube of the present invention to a source of therapeutic agent is clearly an improvement over the required steps of disconnecting the hollow drill from the adapter and hand piece, and of inserting in the hollow drill a dental needle connected to a syringe for injecting the therapeutic agent.

Reconsideration, withdrawal of the rejection, and allowance of the amended claim are respectfully requested.

Claim 3 (currently amended)

Claim 3 further distinguishes over the Kwan reference by specifying that the means for connecting the microtube to the source of the therapeutic agent include a flange. Nothing disclosed by said reference patent in any way resembles a flange affixed to the hollow drill.

Reconsideration, withdrawal of the rejection, and allowance of claim 3 as amended are respectfully requested.

Claim 4 (currently amended)

This claim asserts that the therapeutic agent is a pressurized fluid, for applying pressure at the site of the surgical or dental procedure.

The claim was amended to include the language “a pressurized fluid” in response to the Examiner’s rejection under 35 U.S.C. 112. In making this rejection, the Examiner stated that “the term ‘pressure’ and ‘vacuum’ in claims 4 and 5 are used by the claim to mean ‘therapeutic’, while the accepted meaning is ‘a fluid’.” Applicant acknowledges that he does not understand entirely the meaning which the Examiner intended to convey by the quoted text, but endeavored to respond as best he understood by amending the claim as it now reads. In any case, the pressure or the pressurized fluid is to be understood as a therapeutic agent. How? For example, by staunching bleeding of a gum, using compressed air or other gas. The term “fluid” is generic, and includes liquids, vapors, and gases.

In rejecting the claim under 35 U.S.C. 102(b), the Examiner states that “as to claim 4 – 6, when the syringe applies the agent (col. 3), it also applies the agent with pressure”

Applicant submits that the weak pressure that can be applied using a syringe is not in the same category as the strong pressure of which the claimed microtube is capable by being connected to a gas under pressure. Moreover, if the agent is a liquid, as would generally be the case unless the syringe were empty, such pressurized application would, if anything, increase the bleeding if applied to a bleeding gum.

Reconsideration, withdrawal of the rejections, and allowance of the amended claim are respectfully requested.

Claim 5 (currently amended)

The reasons for inclusion of the words “an evacuated fluid” will be apparent, from the foregoing arguments with respect to claim 4, as a response to the Examiner’s rejection of the claim under 35 U.S.C. 112. Since a complete vacuum, in a dental or surgical operation, is an impossibility, it is acceptable and realistic to speak of “an evacuated fluid,” which in this case would normally be air. Such a fluid is a therapeutic agent by being used, e.g., to remove blood, saliva, and/or fragments of enamel from a patient’s mouth.

In rejecting this claim under 35 U.S.C. 102(b), the Examiner states that “a syringe action can be reversed to cause vacuum action.” As in the case of claim 4 above, applicant submits that the weak vacuum capable of being generated by a syringe is in nowise comparable to that which can be applied by connecting the claimed microtube to a vacuum line. Dental procedures currently use such lines to suction blood, saliva, and/or fragments of enamel from a patient’s mouth. A syringe is never used for such a purpose, for obvious reasons.

Reconsideration, withdrawal of the rejections, and allowance of claim 5 are respectfully requested.

Claim 6 (originally presented)

Claim 6 specifies that the therapeutic agent is a pharmaceutical agent.

It is submitted that by connecting a source of a pharmaceutical agent to the claimed microtube instead of, as taught by Kwan, disassembling the apparatus and inserting in the hollow drill the needle of a dental syringe holding a pharmaceutical agent, there is a significant improvement with regard to time, labor, and general overall efficiency. The same agent may be delivered, but there is a radical and patentable difference in the manner in which it is delivered.

Reconsideration, withdrawal of the rejection, and allowance of claim 6 are respectfully requested.

Claim 7 (currently amended)

Besides the limitations of outside and inside diameter, and the method of fabrication submitted in foregoing arguments for allowability of claim 1, the instant claim includes a further critical limitation; viz., an inner core of a material capable of transmitting a laser beam. The most common material is an optical fiber; however, any material capable of transmitting a laser beam is included in the claim.

For a better understanding of what is implied by “an inner core,” reference is made to **FIG. 2** of the application, and to paragraphs 0015 and 0016 of the specification. The only reason for distinguishing the first and second embodiments of the invention, and for providing different drawings comprising **FIGS. 1** and **2**, is to disclose and claim a core **25** in **FIG. 2**, but not in **FIG. 1**. Otherwise, the embodiments are identical.

What is meant by a core of a material capable of transmitting a laser beam?

“Light waves normally travel in straight lines, but optical fibers can guide them along curved paths The most important point from the user’s standpoint is that optical fibers guide light.” (Jeff Hecht, Understanding Lasers. Indianapolis, Indiana: Howard W. Sams & Company, 1988, p. 152). A copy of the pertinent text is attached to this response.

It will be apparent from the foregoing quotation that, in order for a laser beam to issue from a side port, some material capable of transmitting the beam through the side port is required. Otherwise, the beam would continue to follow a straight line and emerge from the front port. It will therefore be apparent that the second embodiment of applicant’s claimed microtube shown in **FIG. 2** is capable of transmitting a laser beam through the side port **28** by being guided and directed by and following the path of the core material **25**; but that a laser beam entering the hollow drill (1) disclosed by Kwan must necessarily exit the front port (3) and bypass the side port (2).

Thus, not only does the Kwan reference fail to teach or even to suggest the possibility of transmitting a laser beam via the hollow drill (1), but the transmission of such a beam through the side port (2) would be an impossibility, whereas applicant’s microtube **20** is capable of transmitting a laser beam through either a front port **26** or a side port **28**.

As to the material composing the optical fiber, “Fibers are made of glass or plastic that can transmit visible, near-infrared, and near-ultraviolet light. Plastic fibers transmit visible light best, and are more flexible than glass. However, glass fibers have lower loss—particularly at near-infrared wavelengths of 1.0 to 1.6 microns—and thus are preferred for long-distance communications.” (Hecht, op. cit., pp. 152 – 153; copy attached).

Reconsideration, withdrawal of the rejection, and allowance of claim 7 as amended are respectfully requested.

Claim 8 (originally presented)

Clearly, the arguments advanced above for claim 7, based on the core material in the microtube **20**, apply with even greater force to the instant claim, which specifies that the port is a side port. Hence, we are speaking not of the possibility of a side port, not of a potential side port which could be enabled only with a core material capable of transmitting a laser beam through a side port, but of an existing side port. From what has been said above, it will be apparent that applicant’s microtube **20** is fully capable of side-firing a laser beam, but that the prior-art hollow needle (1) is not. As pointed out and documented above, the side port is far more important than a front port in and for this particular application.

Reconsideration, withdrawal of the rejection, and allowance of claim 8 are respectfully requested.

Claim 10 (currently amended)

Besides the limitations of outside diameter and inside diameter, and the method of fabrication submitted in foregoing arguments for allowability of claim 1, claim 10 includes the further limitation of using the claimed microtube for transmitting a therapeutic agent in a surgical or dental procedure. It is submitted that, over and beyond the novelty and non-obviousness of the claimed microtube, the use of the microtube for transmitting a therapeutic agent to the site of a surgical or dental procedure provides an

additional point of novelty and non-obviousness. Not only is the microtube novel and non-obvious per se, but its use in a surgical or dental procedure is neither disclosed nor suggested by the prior art. The hollow drill disclosed by Kwan, while usable in a dental procedure, has none of the qualifying indicia of novelty and non-obviousness inherent in applicant's claimed microtube.

Reconsideration, withdrawal of the rejection, and allowance of claim 10 are respectfully requested.

Claim 11 (currently amended)

Besides the arguments advanced above in support of claim 2, this claim includes the additional limitation of the use of the microtube to transmit the therapeutic agent to the site of the surgical or dental procedure. In doing so, the use of connecting means to connect the tubular member to the source of the therapeutic agent is a significant improvement over the prior-art method of inserting a dental needle into the hollow drill, and connecting the needle to a syringe containing the therapeutic agent. The improvement in saving time and effort, and in overall operational efficiency will be readily apparent to those skilled in the art.

Reconsideration, withdrawal of the rejection, and allowance of the amended claim are respectfully requested.

Claim 12 (currently amended)

Besides the reasons advanced above for allowability of claims 3 and 11, it is submitted that the specific means here recited of a flange further distinguish the present claimed invention over the prior art which, to effect connection to a source of therapeutic agent, in lieu of a flange, employs the inefficient and cumbersome method of filling a dental syringe with the therapeutic agent, and inserting a needle connected to the syringe into the hollow drill disclosed by Kwan.

Reconsideration, withdrawal of the rejection, and allowance of claim 12 are respectfully requested.

Claim 13 (currently amended)

Besides the arguments submitted above in support of claim 6, instant claim has the further limitation of actually using the microtube for the specific function of applying a vacuum (evacuated fluid) at the site of the surgical or dental procedure. Beyond the novelty and non-obviousness inherent in the instrument itself is the novelty and non-obviousness of using the instrument in a surgical or dental procedure in a manner impossible with a syringe. For this reason, and for reasons adduced in support of claim 6, it is submitted that the prior-art method comprising Kwan's hollow drill in no way anticipates or makes obvious the use of the patentably distinct microtube claimed by applicant.

Reconsideration, withdrawal of the rejection, and allowance of claim 13 as amended are respectfully requested.

Claim 14 (originally presented)

In addition to the reasons advanced above in support of claim 6, claim 14 includes the limitation of actually using the microtube to deliver the pharmaceutical agent to the site of the surgical or dental procedure. Over and beyond the points of novelty and non-obviousness of the microtube per se, the method by which the instrument is used in a surgical or dental procedure constitutes and provides additional grounds for patentability. The method disclosed by Kwan for use of a hollow drill to perform certain dental functions is in no way equivalent, anticipatory, or suggestive of the claimed use of applicant's microtube to perform these functions, because the microtube disclosed and claimed by applicant is, for reasons advanced in support of claims 1 and 6, patentably distinct from the hollow drill disclosed by Kwan.

Reconsideration, withdrawal of the rejection, and allowance of claim 14 are respectfully requested.

Claim 15 (currently amended)

The reasons advanced above for allowability of claim 4 (amended) apply in every respect to claim 15. Additionally, since this claim recites a method of using the microtube of claim 4, there is the further qualification inherent in the specific use recited in the claim. It is reiterated that, not only is the claimed microtube patentably distinct from the prior-art hollow drill, but that, as pointed out above in support of claim 4, the degree or amount of pressure which can be applied by the microtube is much greater than the pressure which can be applied with a syringe. The former can be used to staunch bleeding; the latter cannot.

Reconsideration, withdrawal of the rejection, and allowance of claim 15 are respectfully requested.

Claim 16 (currently amended)

This claim recites an original and unique method for an improved root canal.

Here the arguments advanced in support of claim 7 apply with even greater force to the present claim because, by virtue of the extremely limited space available in doing a root canal, only an instrument of dimensions comparable to those of the microtube can be used to carry out the recited functions. That the hollow drill disclosed by Kwan could not be used to deliver a side-fired laser beam to the site of the root canal is apparent for the reason advanced in support of claim 7. Applicant's microtube **20**, however, is fully capable of doing so.

In rejecting claim 16 (as originally presented) under 35 U.S.C. 102(b), the Examiner invoked MPEP 2112.02. This section of the MPEP states that "Under the principles of inherency, if a prior art device, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art device. When the prior art device is the same as a device described in the specification for carrying out the claimed method, it can be assumed the device will inherently perform the claimed process."

From applicant's preceding remarks in support of claim 7 and of the instant claim, it will be apparent that (a) the prior-art device (hollow drill) is not the same as a device (second embodiment of applicant's microtube) described in the specification for carrying out the claimed method; and (b) the prior-art device (hollow drill), in its normal and usual operation, could not perform all of the operations which could be performed by the microtube **20** in the method claimed, because the prior-art drill lacks a core material capable of transmitting a laser beam. Thus, even if size did not preclude using the hollow drill to fire a laser beam during a root canal, the prior-art device would be limited to a front-firing laser, whereas with the claimed microtube **20** both front and side firing of a laser beam are enabled.

In this particular procedure, a root canal, applicant's specification makes it perfectly clear that the side-fired laser beam is the more important: "Use of the microtube **20** as a **side-firing** laser tube combines mechanical canal debridement and chemical canal debridement into a single procedure. It is presently virtually impossible to clean thoroughly a root-canal system with instruments alone. The use of chemical debridement enables removal of vital and/or nonvital pulpal tissue in three-dimensional volume elements which files and conventional instruments cannot reach. **A couple of passes of the side-firing laser tube 20 to the apex of the tooth will clean, debride, and sterilize the site to a greater extent than any existing combination of state-of-the-art procedures.** The side-firing laser tube **20** is so small that it will go all the way down to the apex of the tooth without the need for canal enlargement. It will then sterilize the canal and ablate all pulpal tissue." (Paragraph 0018).

Furthermore, this technology, combined with controlled focal length of the laser, facilitates periapical surgery through the inside of the tooth, all the way through the end of the root from inside the tooth into the diseased bone, which is presently impossible. This enables surgical treatment of diseased tissue in the bone without having to cut large access holes through tissue and bone to get at the disease in the bone, which is now necessary. Presently, apical surgery can be performed only by cutting through the tissue into the bone to access the diseased tissue around the end of the root.

Slicing, cutting, and splitting materials such as potato chips and lunch meat represented the operations of slicing, cutting, and splitting until physicists Fermi and

Einstein took splitting to a different level by splitting the atom. On a more modest scale, such is the case with the microtube laser of the present invention. Macro wrap-around lasers, blunt-nose front-firing lasers, standard reamers, and aspirating syringes represent one thing; but the precision side-firing laser built on technology based on the scientific principles discovered by physicists, using electroplating, represents a different order of magnitude, and is qualitatively as well as quantitatively different and distinct from the prior-art technology. The microtube precision side-firing laser opens boundless opportunities for surgeons, oral surgeons, and dentists; it is a totally different entity.

Reconsideration, withdrawal of the rejection, and allowance of claim 16 are respectfully requested.

Claim 17 (currently amended)

In addition to applicant's remarks in support of claim 10, above, which are equally cogent and relevant to the present claim, there is the additional consideration of space limitation inherent in doing a root canal. It is submitted that the size of the prior-art device (1) precludes its use for carrying out the claimed method.

Reconsideration, withdrawal of the rejection, and allowance of claim 17 are respectfully requested.

Claim 18 (currently amended)

The reasoning applied to claims 8 and 16 above apply with equal force to the present claim, which specifies that the port used is a side port. As argued above in support of claim 8, firing a laser from a side port is possible only by using the claimed microtube 20, and not by using the prior-art device (1).

Reconsideration, withdrawal of the rejection, and allowance of claim 18 are respectfully requested.

Claim 19 (currently amended)

In addition to applicant's remarks in support of claim 11, above, which are equally cogent and relevant to the present claim, there is the consideration of space limitation inherent in doing a root canal. The extremely limited space available for carrying out this particular dental procedure rules out the possibility of supplying a sealant by means of a syringe and dental needle.

Reconsideration, withdrawal of the rejection, and allowance of claim 19 are respectfully requested.

Claim 20 (currently amended)

The arguments applied above for allowability of claim 12 apply with even greater cogency to claim 20, because of the severely limited space available in carrying out the dental procedure for a root canal. It is reiterated that, as stated above for claim 19, space limitations preclude the use of a dental syringe and needle.

Reconsideration, withdrawal of the rejection, and allowance of claim 20 are respectfully requested.

SUMMARY, CONCLUSIONS, AND PETITION

In conclusion, it is submitted that, in view of the amendments and arguments for patentability presented herein, the application is in condition for allowance.

Reconsideration, withdrawal of the rejections, and allowance of the application are respectfully requested.

Respectfully submitted

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Sept. 14, 2004

Date of Signature

Attachments/Enclosures

section as shown in FIGS. 1C and 1D, enabling the adapter, 7, to transmit rotational movement from a standard contra-angle dental handpiece to the drill, 1. The shank, 8, of the adapter, 7, is shaped to fit the chuck of a standard contra-angle dental handpiece. As supplied, the drill, 1, is protected by a removable cap, 9, and the whole assembly is supplied in a sterile condition in a disposable wrapper.

OPERATION FIG. 1

The manner of operation of the present invention is simple. The dental practitioner selects the site where he wishes to pierce the patient's cortical bone and applies a local anesthetic into the gingival tissue with a conventional dental syringe. The shank of the apparatus, 7, is fitted into the chuck of a standard contra-angle dental handpiece and the protective cap, 9, removed. The drill is then applied at the selected anesthetized site until the cortical bone is penetrated. By restraining the drill using the lip, 5, the said handpiece and adapter, 7, are then removed. Using a conventional dental syringe, which may be the same one as used for the foregoing local anesthesia, the dental needle is inserted into the drill, 1, facilitated by the funnel shaped orifice, 6, and the required quantity of anesthetic solution slowly injected into the cancerous bone. The dental needle is then withdrawn following which the drill, 1, is also removed and safely disposed of, together with the adapter, 7, and the conventional dental needle.

CONCLUSION, RAMIFICATIONS AND SCOPE

Accordingly the reader will see that the intraosseous drill of this invention can be used to safely facilitate the introduction of anesthetic solution to a patient's jaw for dental purposes. Its operation is simple and reliable. By placing the perforations, 2, in the wall of the drill, 1, as shown in FIG. 1B, the risk of blocking the path of the anesthetic solution with bone fragments during drilling is eliminated even if the beveled cutting end of the drill is blocked, and by using the hollow drill as a guide for the subsequent insertion of a conventional dental needle, the risk of the dental practitioner experiencing difficulty in finding, or even being unable to find the hole in the cortical bone, as happens in other systems, is also eliminated. Furthermore the present invention has the advantages that

- a) it is cheap to manufacture compared with other complex systems
- b) it requires the use of a standard contra-angle dental handpiece which virtually every dental practitioner already has available
- c) because the whole assembly is so short, access to difficult parts of the patient's mouth is facilitated and the patient's discomfort reduced to a minimum
- d) it requires no special techniques or particular training for the dental practitioner to be able to use it effectively
- e) by being completely disposable it obviates the risk of spreading infectious diseases.

Although the foregoing description contains many specificities, these should not be construed as limiting the scope of the invention but as merely providing illustrations of some of the currently preferred embodiments of the invention. For example, the mating surfaces of the hub, 4, and the adapter, 7, may be of many shapes other than hexagonal, from square to splined. The material from which both the hub, 4, and the adapter, 7, are made may be plastics or metal. The beveled cutting end of the drill may be closed.

The configuration of the perforations, 2, may be such that their direction relative to the cross-section of the drill, 1, is from radial to almost tangential, and their shape may be circular or elliptical or any other

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FIBER OPTICS

Light waves normally travel in straight lines, but optical fibers can guide them along curved paths. The main use of optical fibers is to carry communication signals over long distances, but they also can be used in other types of optical systems.

A simplified view of the working of an optical fiber is shown in Figure 5-6. Light is transmitted by the core, which has a refractive index n_1 , and is surrounded by a cladding layer with a lower refractive index n_2 . If light in the core strikes the interface with the cladding at a glancing angle, it is reflected back into the core, because of the phenomenon of total internal reflection that we discussed briefly in Chapter 2. Light striking at larger angles leaks into the cladding layer and ultimately can escape from the fiber itself.

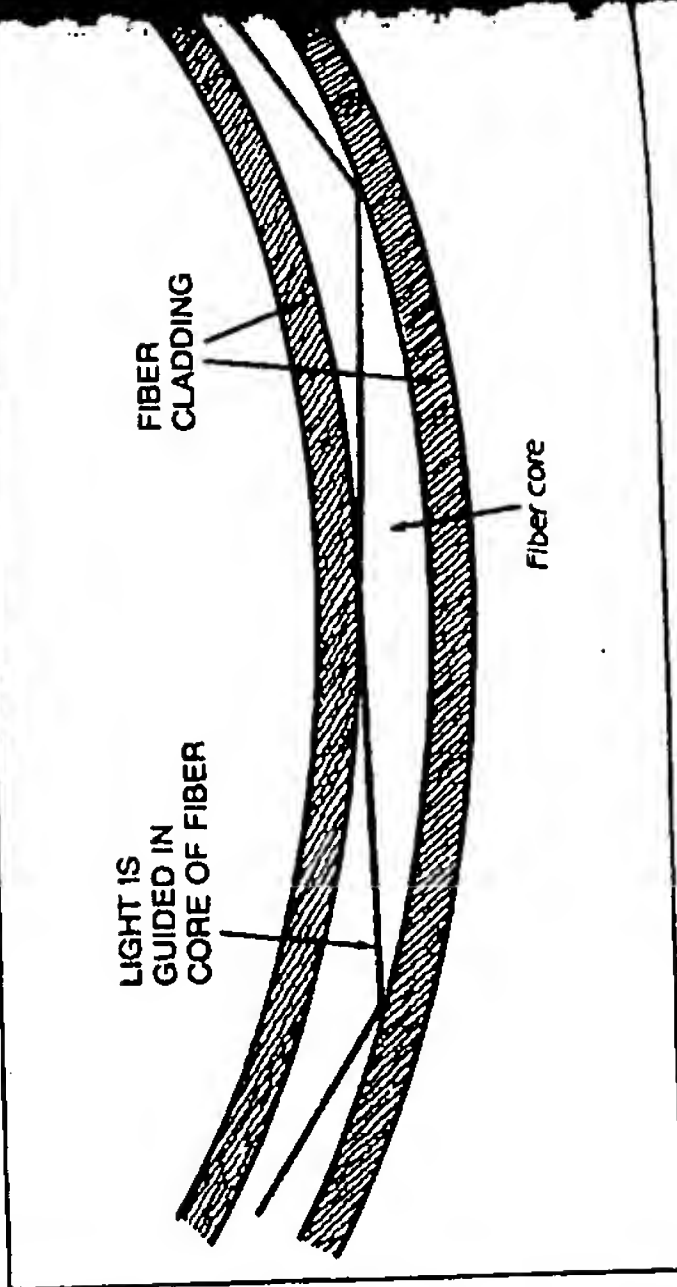


Figure 5-6. Light guiding in an optical fiber.

We should stress that this is a simplified view of how light travels through optical fibers. The subtleties are treated in more detail in a companion volume, *Understanding Fiber Optics*. * The most important point from the user's standpoint is that optical fibers guide light.

Fibers are made of glass or plastic that can transmit visible, near-infrared, and near-ultraviolet light. Plastic fibers transmit

* *Understanding Fiber Optics*, (Cat. No. 27066), by Jeff Hecht, Howard W. Sams & Company, 1987.

and are more flexible than glass. However, glass loss—particularly at near-infrared wavelengths of meters—and thus are preferred for long-distance

are usually used for communications, where they are generated by semiconductor lasers over long distances. tied together to "pipe" light into hard-to-reach places the human body), or to carry images from point to edles may be made rigid (by melting the fibers ble (by leaving individual fibers loose in a housing). bundles are used to deliver laser light for some

medicine and industry. technology for making fibers from plastic or silica glass is However, it is hard to make fibers from other optical work is underway on fibers for wavelengths longer ers for potential applications with carbon-dioxide types in medicine and industry. However, serious in to be overcome with the materials.

OPTICS

indicates the direction of the oscillating electric of a light wave. As we mentioned earlier, you can two orthogonal polarizations, with electric fields to each other. The simplest way to think of polarization the X-Y plane, as shown in Figure 5-7. The vector origin (0,0) to a point on the plane, and measures the direction of the electric field. Each polarization vector perpendicular vectors, one in the X direction, the direction. Those two vectors are the horizontal and tion components.

XY directions are not absolute. If you rotate the two in break the polarization vector into two components aligned along the two new axes. The two component vectors will differ, but their sum will

separate light into its polarization components. film polarizers (like those used for sunglasses) absorb along one axis, and transmit light polarized along the other. For example, a polarizer might transmit light polarized